

PATENT Attorney Matter No. 4239-66491-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Szu et al.

Patent No. 6,858,211

Issued: February 22, 2005 **Application No.** 09/744,289

Filed: August 1, 2001 Confirmation No. 3981

For: VACCINES AGAINST ESCHERICHIA

COLI 0157 INFECTION

Examiner: Virginia Allen Portner

Art Unit: 1645

Attorney Reference No. 4239-66491-01

CERTIFICATE OF MAILING

I hereby certify that this paper and the documents referred to as being attached or enclosed herewith are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: COMMISSIONER FOR PATENTS, ATTN: CERTIFICATE OF CORRECTIONS BRANCH, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450 on the date shown below.

Attorney or Agent for Applicant(s)

Date Mailed June 5, 2006

COMMISSIONER FOR PATENTS

ATTN: CERTIFICATE OF CORRECTIONS BRANCH

P.O. BOX 1450

ALEXANDRIA, VA 22313-1450

Certificate

JUN 1 2 2006

of Correction

REQUEST FOR CERTIFICATE OF CORRECTION

The following printing errors were noted in comparing the printed patent with the papers in the attorneys' files:

On the Cover, under References Cited, OTHER PUBLICATIONS:

"Bitzan Me t al, Infection..." should read --Bitzan, M. et al., Infection...-.

"Konadu EY et al., Nov. 1994, Infection and Immunity, Vool 62(11)..." should read --Konadu EY et al., Nov. 1994, Infection and Immunity, vol. 62(11)...-.

"Harari, I et al., Infection adn Immunity..." should read --Harari, I et al., Infection and Immunity...-.

"... Escherichia coli of serotypes O157:h7 and O26:H11..." should read --... Escherichia coli of serotypes O157:H7 and O26:H11...-.

"Konadu et al., Jun. 26, 1997, Seide presentation..." should read --Konadu et al., Jun. 26, 1997, Slide presentation...-.

Request for Certificate of Correction - Page 1 of 5

06/08/2006 NNGUYEN1 00800056 6858211

01 FC:1811

198.89 OP

JUN 12 2006

"Chu, C; Preparation, Characterization, an Immunogencity..." should read -- Preparation, Characterization, and Immunogenicity...-.

"Gupta, R.K., "Comparitive Immunogencity of Conjugates Composed of Escherichia coli 0111 0-Specific..." should read --Comparative Immunogenicity of Conjugates Composed of Escherichia coli 0111 0-Specific....--.

"Konadu et al., "Investigational Vaccine for *Escherichia coli* 0157: Phase 1 Study of 0157..." should read --Investigational Vaccine for *Escherichia coli* O157: Phase 1 Study of O157...-.

"Konadu et al., "Preparation, Characterization and Immunological Properties in Mice of *Escherichia coli* 0157 0-Specific..." should read --Preparation, Characterization and Immunological Properties in Mice of *Escherichia coli* O157 O-Specific...-

"Taylor et al., Synthesis, Characterization, and Clinical Evaluation of Conjugate Vaccines Composed of the 0-Specific..." should read --Taylor et al., Synthesis, Characterization, and Clinical Evaluation of Conjugate Vaccines Composed of the O-Specific...-.

"Human Testing of E. coli 0157:H7..." should read --Human Testing of E. coli 0157:H7...-.

"...Anti-LPS IgG (Preliminary Slide)." should read --...Anti-LPS IgG (Preliminary Slide)).--.

"Scheerson, et al., "Quantitative and Qualitative Analyses..." should read --Schneerson, et al., "Quantitative and Qualitative Analyses..."--.

On the Cover, in the last sentence of the first paragraph in the Abstract:

"The conjugates, and compositions thereof, are useful as vaccines to induce serum antibodies which have bactericidal or bacteriostatic activity against against *E. coli*, in particular..." should read --The conjugates, and compositions thereof, are useful as vaccines to induce serum antibodies which have bactericidal or bacteriostatic activity against *E. coli*, in particular...-.

In the Specification:

Column 1, lines 12, 22, 25, 26, 29, 32 and 65, "O517" should read --O157--.

Column 1, line 13, "...methods of using of these conjugates and/or compositions..." should read --...methods of using these conjugates and/or compositions...--.

Column 2, lines 5, 17, 18, 20, 21, 22, 26, 32, 35, 38 and 49, "O517" should read --O157--.

Column 2, line 41, "E. coil" should read -- E. coli--.

Column 3, line 7, "(≥ 100kD)" should read --(≤ 100kD)--.

Column 3, line 15, "B cell" should read --B-cell--.

Column 3, lines 27, 30, 45, 46, 52, 54, 57 and 63, "O517" should read --O157--.

Column 3, lines 54-55, "There also remains a need compositions..." should read -- There also remains a need for compositions...-.

Column 3, line 64, "...and compositions thereof, and to methods of using of these..." should read --...and compositions thereof, and to methods of using these...-.

Column 4, lines 7, 11, 13, 22, 27, 32, 41, 64, 65 and 67, "O517" should read --O157--.

Column 4, lines 9-10, "...bacteriostatic activity against *E. coli*..." should read --...bacteriostatic activity against *E. coli*...-.

Column 5, lines 9, 11, 13, 14, 15, 18, 19, 22, 26, 30, 31, 37, 38, 42, 47, 51, 56, 58, 60, and 65 should read --O157--.

Column 6, lines 9, 12, 15, 17, 18, 22, and 23, "O517" should read --O157--.

Column 6, line 17, "Additionally, it is may be used..." should read -- ... Additionally, it may be used...-.

Column 7, lines 54 and 63, "O517" should read --O157--.

Column 8, lines 11, 25, 47, 55, and 58, "O517" should read --O157--.

Column 9, lines 13, 32, 43, 56, and 61, "O517" should read --O157--.

Column 10, lines 3, 22, 25, and 52, "O517" should read --O157--.

Column 10, line 48 "booster infections..." should read --booster injections...--.

Request for Certificate of Correction - Page 3 of 5

Column 10, line 59 "Geometic mean antibody level (ELISA units)" should read --Geometric mean antibody level (ELISA units--.

Column 12, lines 1, 45, and 46, "O517" should read --O157--.

Column 12, line 4 "...the FDA (BB-IND:5528) and the..." should read --...the FDA (BB-IND-5528) and the...-.

Column 13, lines 14, 18, and 67, "O517" should read --O157--.

Column 13, line 28, "...with either of the two DeA-LPS-rFPA conjugates..." should read --...with either of the two DeA-LPS-rEPA conjugates...-.

Column 14, Table 3A, line 40, "32.8 (23.51)" should read --32.8 (23-51)--.

Column 15, Table 4, line 50, ">1.3 x 10^4 " should read -->1.3 x 10^3 --.

Column 16, Table 5, line 4, "... Escherichia coli 0157 O-specific..." should read --... Escherichia coli 0157 O-specific...-.

Column 16, lines 18, 21, and 28, "O517" should read --O157--.

Column 16, line 23, "Shigella toxin 1 (StxB1)..." should read --Shigella toxin I (StxB1)...-.

Column 17, lines 12, 14, 46, 48, 57, and 62, "O517" should read --O157--.

Column 18, lines 5, 6, 10, 12, 17, 21, 43, 51, 52, and 64, "O517" should read --O157--.

Column 18, line 59, "...point to LPD..." should read --...point to LPS...-.

Column 19, lines 1 and 6, "O517" should read --O157--.

Column 19, line 34, "6. Riley. L. W.," should read --6. Riley, L. W.,--.

Column 19, lines 41-42, "177 383-387" should read --177, 383-387--.

Column 19, line 56, "91991)." should read --(1991).--.

Column 20, line 4, "Immun. 59 4555-4561(1991)." should read --Immun. 59, 4555-4561 (1991).--.

Column 20, line 6, "J. Exp. Med. 166 1510-1524(1987)." should read --J. Exp. Med. 166, 1510-1524 (1987).--.

Column 20, line 9, "Bockemühl, J.,. Int." should read --Bockemühl, J., Int.--.

Column 20, line 15, "Gentry M., Dalrymple J.M.," should read -- Gentry M., Dalrymble J.M.,--.

Column 20, line 28, "J. Clin Microbial.," should read -- J. Clin. Microbiol., --.

Column 20, line 31, "Lance" should read --Lancet ---

Column 20, line 36, "Infect. Di.s J.," should read --Infect. Dis. J.,--.

A Certificate of Correction is enclosed in duplicate to make formal notice of the errors in the referenced patent. Also enclosed is a check in the amount of \$100 for payment of the Certificate of Correction fee.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

By

Anne Carlson, Ph.D.

Registration No. 47,472

One World Trade Center, Suite 1600 121 S.W. Salmon Street Portland, Oregon 97204

Telephone: (503) 226-7391 Facsimile: (503) 228-9446

'UN 0 7 2006 🗒

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In reapplication of: Szu et al.

Patent No. 6,858,211

Issued: February 22, 2005 **Application No.** 09/744,289

Filed: August 1, 2001 Confirmation No. 3981

For:

VACCINES AGAINST ESCHERICHIA COLI

0157 INFECTION

Examiner: Virginia Allen Portner

Art Unit: 1645

Attorney Reference No. 4239-66491-01

CERTIFICATE OF MAILING

I hereby certify that this paper and the documents referred to as being attached or enclosed herewith are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: COMMISSIONER FOR PATENTS, ATTN: CERTIFICATE OF CORRECTIONS BRANCH, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450 on the

date shown below.

Attorney or Agent for Applicant(s)

Date Mailed June 5, 2006

COMMISSIONER FOR PATENTS

ATTN: CERTIFICATE OF CORRECTIONS BRANCH

P.O. BOX 1450

ALEXANDRIA, VA 22313-1450

TRANSMITTAL LETTER

Enclosed for filing in the application referenced above are the following:

- ∠
 ✓ Letter Requesting Certificate of Correction.
- Certificate of Correction.
- \square Check in the amount of \$100.00 to cover fee Certificate of Correction fee.
- The Director is hereby authorized to charge any fees that may be required, or credit overpayment, to Account No. 02-4550. A copy of this sheet is enclosed.
- Please return the enclosed postcard to confirm that the items listed above have been received.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

Ву

Arme Carlson, Ph.D. Registration No. 47,472

One World Trade Center, Suite 1600

121 S.W. Salmon Street Portland, Oregon 97204

Telephone: (503) 226-7391 Facsimile: (503) 228-9446

cc:

Docketing

UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

PATENT NO. : 6,858,211

DATED

: February 22, 2005

INVENTOR(S) : Szu et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Cover, under References Cited, OTHER PUBLICATIONS:

"Bitzan Me t al, Infection..." should read -- Bitzan, M. et al., Infection...-.

"Konadu EY et al., Nov. 1994, Infection and Immunity, Vool 62(11)..." should read ---Konadu EY et al., Nov. 1994, Infection and Immunity, vol. 62(11)...-.

"Harari, I et al., Infection adn Immunity..." should read --Harari, I et al., Infection and Immunity...-.

"...Escherichia coli of serotypes O157:h7 and O26:H11..." should read --...Escherichia coli of serotypes O157:H7 and O26:H11...-.

"Konadu et al., Jun. 26, 1997, Seide presentation..." should read --Konadu et al., Jun. 26, 1997, Slide presentation...-.

"Chu, C; Preparation, Characterization, an Immunogencity..." should read -- Preparation, Characterization, and Immunogenicity...-.

"Gupta, R.K., "Comparitive Immunogencity of Conjugates Composed of *Escherichia coli* 0111 0-Specific..." should read --Comparative Immunogenicity of Conjugates Composed of *Escherichia coli* 0111 0-Specific.....--.

"Konadu et al., "Investigational Vaccine for *Escherichia coli* 0157: Phase 1 Study of 0157..." should read --Investigational Vaccine for *Escherichia coli* O157: Phase 1 Study of O157...-.

"Konadu et al., "Preparation, Characterization and Immunological Properties in Mice of *Escherichia coli* 0157 0-Specific..." should read --Preparation, Characterization and Immunological Properties in Mice of *Escherichia coli* O157 O-Specific...-.

"Taylor et al., Synthesis, Characterization, and Clinical Evaluation of Conjugate Vaccines Composed of the 0-Specific..." should read --Taylor et al., Synthesis, Characterization, and Clinical Evaluation of Conjugate Vaccines Composed of the O-Specific...--.

"Human Testing of E. coli 0157:H7..." should read --Human Testing of E. coli 0157:H7...-.

"...Anti-LPS IgG (Preliminary Slide)." should read --...Anti-LPS IgG (Preliminary Slide)).--.

MAILING ADDRESS OF SENDER: Klarquist Sparkman, LLP One World Trade Center, Suite 1600 121 SW Salmon Street Portland, Oregon 97204 PATENT NO. 6,858,211 No. of add'l copies 0 (@ .30 per page) "Scheerson, et al., "Quantitative and Qualitative Analyses..." should read --Schneerson, et al., "Quantitative and Qualitative Analyses..."--.

On the Cover, in the last sentence of the first paragraph in the Abstract:

"The conjugates, and compositions thereof, are useful as vaccines to induce serum antibodies which have bactericidal or bacteriostatic activity against against *E. coli*, in particular..." should read --The conjugates, and compositions thereof, are useful as vaccines to induce serum antibodies which have bactericidal or bacteriostatic activity against *E. coli*, in particular...--.

In the Specification:

Column 1, lines 12, 22, 25, 26, 29, 32 and 65, "O517" should read --O157--.

Column 1, line 13, "...methods of using of these conjugates and/or compositions..." should read --...methods of using these conjugates and/or compositions...-.

Column 2, lines 5, 17, 18, 20, 21, 22, 26, 32, 35, 38 and 49, "O517" should read --O157--.

Column 2, line 41, "E. coil" should read -- E. coli--.

Column 3, line 7, "(≥ 100 kD)" should read --(≤ 100 kD)--.

Column 3, line 15, "B cell" should read -- B-cell--.

Column 3, lines 27, 30, 45, 46, 52, 54, 57 and 63, "O517" should read --O157--.

Column 3, lines 54-55, "There also remains a need compositions..." should read -- There also remains a need for compositions...-.

Column 3, line 64, "...and compositions thereof, and to methods of using of these..." should read --...and compositions thereof, and to methods of using these...-.

Column 4, lines 7, 11, 13, 22, 27, 32, 41, 64, 65 and 67, "O517" should read --O157--.

Column 4, lines 9-10, "...bacteriostatic activity against *E. coli*..." should read --...bacteriostatic activity against *E. coli*...-.

Column 5, lines 9, 11, 13, 14, 15, 18, 19, 22, 26, 30, 31, 37, 38, 42, 47, 51, 56, 58, 60, and 65 should read --O157--.

Column 6, lines 9, 12, 15, 17, 18, 22, and 23, "O517" should read --O157--.

Column 6, line 17, "Additionally, it is may be used..." should read --...Additionally, it may be used...-.

Column 7, lines 54 and 63, "O517" should read --O157--.

Column 8, lines 11, 25, 47, 55, and 58, "O517" should read --O157--.

Column 9, lines 13, 32, 43, 56, and 61, "O517" should read --O157--.

MAILING ADDRESS OF SENDER: Klarquist Sparkman, LLP One World Trade Center, Suite 1600 121 SW Salmon Street Portland, Oregon 97204 PATENT NO. 6,858,211
No. of add'l copies 0
(@ .30 per page)

Column 10, lines 3, 22, 25, and 52, "O517" should read --O157--.

Column 10, line 48 "booster infections..." should read --booster injections...--.

Column 10, line 59 "Geometic mean antibody level (ELISA units)" should read --Geometric mean antibody level (ELISA units--.

Column 12, lines 1, 45, and 46, "O517" should read --O157--.

Column 12, line 4 "...the FDA (BB-IND:5528) and the..." should read --...the FDA (BB-IND-5528) and the...-.

Column 13, lines 14, 18, and 67, "O517" should read --O157--.

Column 13, line 28, "...with either of the two DeA-LPS-rFPA conjugates..." should read --...with either of the two DeA-LPS-rEPA conjugates...-.

Column 14, Table 3A, line 40, "32.8 (23.51)" should read --32.8 (23-51)--.

Column 15, Table 4, line 50, ">1.3 x 10⁴" should read -->1.3 x 10³--.

Column 16, Table 5, line 4, "... Escherichia coli 0157 O-specific..." should read --... Escherichia coli 0157 O-specific...-.

Column 16, lines 18, 21, and 28, "O517" should read --O157--.

Column 16, line 23, "Shigella toxin 1 (StxB1)..." should read --Shigella toxin I (StxB1)...-.

Column 17, lines 12, 14, 46, 48, 57, and 62, "O517" should read --O157--.

Column 18, lines 5, 6, 10, 12, 17, 21, 43, 51, 52, and 64, "O517" should read --O157--.

Column 18, line 59, "...point to LPD..." should read --...point to LPS...-.

Column 19, lines 1 and 6, "O517" should read --O157--.

Column 19, line 34, "6. Riley. L. W.," should read --6. Riley, L. W.,--.

Column 19, lines 41-42, "177 383-387" should read --177, 383-387--.

Column 19, line 56, "91991)." should read -- (1991).--.

Column 20, line 4, "Immun. 59 4555-4561(1991)." should read --Immun. 59, 4555-4561 (1991).--.

Column 20, line 6, "J. Exp. Med. 166 1510-1524(1987)." should read --J. Exp. Med. 166, 1510-1524 (1987).--.

Column 20, line 9, "Bockemühl, J.,. Int." should read --Bockemühl, J., Int.--.

Column 20, line 15, "Gentry M., Dalrymple J.M.," should read -- Gentry M., Dalrymble J.M.,--.

Column 20, line 28, "J. Clin Microbial.," should read -- J. Clin. Microbiol., --.

Column 20, line 31, "Lance" should read -- Lancet ---

Column 20, line 36, "Infect. Di.s J.," should read --Infect. Dis. J.,--.

MAILING ADDRESS OF SENDER: Klarquist Sparkman, LLP One World Trade Center, Suite 1600 121 SW Salmon Street Portland, Oregon 97204

PATENT NO. 6,858,211 No. of add'l copies 0 (@ .30 per page)